



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

M

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 09/881,736 | 06/18/2001 | Michael Glotzer | 0652.2260001/EKS/AES | 8755 |
| 26111 | 7590 | 06/15/2004 | EXAMINER | |
| STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005 | | | LI, RUIXIANG | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1646 | | |
| DATE MAILED: 06/15/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/881,736 | GLOTZER ET AL. | |
| | Examiner | Art Unit | |
| | Ruixiang Li | 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 and 11-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 11, 12 and 34-44 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 13-33 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/18/2002.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The amendment filed on March 9, 2004 has been entered in full. Claims 7-10 have been canceled. Claims 13-44 have been added. Claims 1-6 and 11-44 are pending. Claims 13-33 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Withdrawn Objections and/or Rejections

Applicants' cancellation of claims 7-10 has made all the rejections and objections set forth in the previous office action (Paper No. 13, September 9, 2003) moot.

III. Information Disclosure Statement

The information disclosure statement that was originally filed on January 18, 2002 has been considered by the Examiner and a signed copy of the substitute form PTO-1449 is attached to the office action.

IV. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 26 is drawn to a method for identifying a compound capable of modulating cytokinesis comprising determining said compound's ability to interfere with the ability of a CYK-4 GTPase activating (GAP) or fragment thereof to interact with a member of the MKLP1 subfamily of kinesin-like protein. Clearly, the sequence of the MKLP1 is essential to practice the claimed invention. Without the sequence information, one cannot practice the claimed invention. The sequence cannot be incorporated by references other than to issued U. S. patents or U.S. patent applications to be issued. See, MPEP §608.01(p)(page 600-79). In the instant case, the sequences of the MLKP1 family members are referred to GenBank database (5th paragraph of page 30).

It is noted that Applicant is also required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). The attempt to incorporate subject matter into this application by reference to a commercial sequence database is improper because such a database is subject to change and correction. It is imperative that the sequence as it was known at the time of filing is disclosed in the specification.

V. Claim Rejections under 35 USC § 112, 2nd paragraph

New claims 13-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) New claims 13-33 are indefinite because the steps of the methods do not necessarily achieve the goal set forth in the claim preamble. It is unclear how a candidate modulator is selected, determined, and correlated to the preamble.

Applicants argue that new claims 14 and 24 recite steps for the methods recited in new claims 13 and 23. Moreover, each of new claims 14 and 24 recite language that correlates the recited steps in the claim to the preamble of the claim.

This has been fully considered, but is not deemed to be persuasive because the steps of method recited in claim 14 and 24 still do not correlate to the preamble of the claim: identifying a compound capable of modulating cytokinesis. It is unclear from the specification that there is a direct link between “modulating cytokinesis” and “modulating the ability of a CYK-4 GAP to promote GTP hydrolysis by a Rho family GTPase”. Furthermore, the essential steps in claims 13 and 23 are missing. It is noted that each method should have necessary steps linking to the preamble of the claim.

(ii) New claims 13-15, 20-27, 31-33 are indefinite because they recite acronyms “CYK-4” and “MKLP1”. Applicants argue that new claims 13 and 23 each recites language supported by the specification, that, in addition to the acronyms identifying CYK-4 and/or MKLP1, describes each of the proteins. Applicants further submit that new claims 23 recites “a member of the MKLP1 subfamily of kinesin-like proteins” and,

in new claims that explicitly recite human CYK-4, the identifying phrase “SEQ ID NO: 2” is recited as well.

This has been fully considered, but is not deemed to be persuasive because the change of the language recited in the claims does not change the fact that the acronyms are still used in the claims and recitation of SEQ ID NO: 2, for example, in claims 16 and 17, does not define and limit the scope of invention in other claims that do not recite a sequence identifier.

(iii) New claims 23-33 are indefinite because each claim recites the term “interact” or “interaction”. Applicants argue that the term “interaction” is used throughout the specification to indicate binding and/or association in a complex. This is not persuasive because there is no unambiguous definition of the term “interaction” such that one skilled in the art would know the metes and bounds of the term. If the term “interact” is intended to mean “binding”, the claims should be amended so.

(iv) New claim 13 23, and 25 are indefinite because claim 13 recites “a GAP domain” in line 4, whereas claims 23 and 25 recite “a domain of said CYK-4 GTPase activating protein”. Since neither the art nor the specification defines the terms unambiguously, the claims are indefinite.

(v) New claim 30 is indefinite because it recites “the N-terminal region containing amino acids 1-120”. It is unclear what is referred by the term.

VI. Claim Objections

Claims 13-16, 18, 20-26, 28, and 30-33 are objected to because they recite non-elected subject matter.

Applicants argue that new claims 13-33 recite only elected subject matter. The generic claims are permitted in an application during prosecution, after an election of species had been made. This is not found to be persuasive. While claims that recite more than one elected species are permitted in an application during prosecution, those claims will remain objected to during prosecution. The Examiner clarifies that the restriction to a single CYK-4 polypeptide in Paper No. 1o (April 17, 2003) is not a species election; rather it sets forth additional invention groups. In the instant case, Applicants elected human CYK-4 polypeptide.

VII. Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Gary.Kunz@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Ruixiang Li
Examiner
June 2, 2004

Gary d. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600